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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,965

03/22/2004

Alain Rambach

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2331

8791 7590 11/07/2007  
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EXAMINER
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MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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11/07/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/806,965	Applicant(s) RAMBACH ET AL.	
	Examiner Irene Marx	Art Unit 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8/30/07.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 7 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/30/07 has been entered.

The application should be reviewed for errors. Error occurs, for example, in the recitation of "a bacteria" in claim 7. This is grammatically incorrect since "bacteria" is the plural of "bacterium".

Claim 7 and 13 are being considered on the merits.

Claims 1-6 and 8-11 are withdrawn from consideration as directed to a non-elected invention.

### ***Specification***

The amendment filed 8/30/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The replacement of X-acglmn to GlcNac at least at pages 4, 6, 7 and 13.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 13 are vague, indefinite and confusing in the recitation of "of X-Phos, X-GlcNac, Mag-Gal, Mag- $\alpha$ -Gal, and Mag-Phos" in the absence of definitions for these compositions in the as filed specification. The definition X-Phos AMPD salt is noted. None of

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the other terms are defined with any particularity in the document attached. The relationship between Mag-Gal and Magenta-Gal is uncertain. In this regard, see also the new matter rejections regarding the replacement of "X-acglmn", for example with "X-GlcNac".

Claim 7 is confusing in the recitation "b) detecting a bacteria based on an appearance of a color in the medium associated with the bacteria while the cultured sample remains in the anaerobic conditions", since there is no clear indication in the claim as to how to identify bacteria using this process, particularly with any "oxidizing metal complex capable of oxidative polymerization of an indoxyl chemical derivative" or even when using ammoniacal iron citrate. The "detection" does not set forth how "an appearance of a color" is "associated with the bacteria". Therefore, it is unclear how the method is intended to "detect" any bacteria, or in particular specific bacteria..

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12, 14, 15-18 and 20 of copending Application No. 11/011798. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because they are directed to the same subject matter of detecting bacteria by using an indoxyl derivative in combination with a compound such as ammoniacal iron citrate to produce colored precipitates and/or colored colonies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman *et al.* (Molecular Microbiology (1999), vol. 33, No. 1, pages 18-32) taken with Dartois *et al.* (Journal of Bacteriology, Apr. 1998, Vol. 180, No. 7, p. 1855-1861) and Chevalier *et al.*

The claims appear to be directed to a method for the detection of bacteria, wherein the bacteria are cultured anaerobically in a medium comprising an oxidizing metal complex, such as ammoniacal iron citrate and a substrate containing an indoxyl derivative such as X-gal..

Newman *et al.* disclose a method of detection of bacteria wherein the bacteria are grown on solid media comprising iron citrate and X-gal and wherein the bacterial colonies are detected by colored halos. See, e.g., Figure 3. The reference does not specifically indicate that the iron citrate product used is ammoniacal iron citrate. However, this product is recognized in the art to be useful in microbiology in conjunction with X-gal for screening and detection processes as shown by Dartois *et al.*. See, e.g., page 1856, paragraph 2. One of ordinary skill in the art would reasonably have expected polymerization to occur in the processes of Newman *et al.* and Dartois *et al.* in view of the presence of reactants comprising an oxidizing metal complex and at least one substrate containing an indoxyl derivative, in the absence of evidence to the contrary.

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The references differ from the invention as claimed in that anaerobicity is not specifically disclosed. However, Chevalier *et al.* disclose a method of detecting bacteria grown anaerobically (page 77, last two lines) using X-gal as the substrate in a similar environment. Thus one of ordinary skill in the art would reasonably have expected this compound to be effective at anaerobic conditions.

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in detecting anaerobic bacteria by modifying the process of Newman *et al.* by using ferric ammonium citrate (ammoniacal iron citrate) as suggested by the teachings of Dartois *et al.* and using anaerobicity as taught by Chevalier *et al.*, for the expected benefit of detecting anaerobic bacteria, and anaerobic pathogens in particular, more effectively and efficiently.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the detecting process of bacteria when using ferric citrate in conjunction with X-gal as taught by Newman *et al.* by using ferric ammonium citrate (ammoniacal iron citrate) in conjunction with X-gal as suggested by the teachings of Dartois *et al.* and using anaerobicity as taught by Chevalier *et al.* in a process of detecting anaerobic bacteria for the expected benefit of detecting and differentiating a greater variety of pathogenic and deleterious bacteria in food and water, for example, with a more sensitive and effective detection test.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

### **Response to Arguments**

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the crux of the invention is the "anaerobic" aspect of cultivation. However, it is unclear that the results of aerobic cultivation differ significantly over those for anaerobic cultivation, since the same chemical reactions are involved, and there is nothing in the claimed invention to direct one of ordinary skill in the art to the detection of particular bacteria whether aerobic or anaerobic.

It is noted that the results in the specification are directed to the cultivation and detection of specific microorganisms, such as specific species of *Clostridium* with specific media, which

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produce interesting results. There is no clear indication that these results can reasonably be extrapolated to the cultivation of any anaerobic bacteria in any medium containing any one of X-Gal, X-Phos, X-GlcNac ("X-acglmn"), Mag-Gal, Mag- $\alpha$ -Gal, and Mag-Phos and any oxidizing metal complex capable of oxidative polymerization of an indoxyl chemical derivative or ammoniacal ferric citrate.

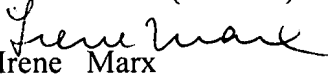
The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
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